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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/428,203	10/27/1999	CHRISTOPHER O. OKUNJI	003/172/SAP	4366

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EXAMINER

FLOOD, MICHELE C

ART UNIT PAPER NUMBER

1655

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/428,203

Applicant(s)

OKUNJI ET AL.

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 2-10, 13-29, 32-35 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 11, 12, 30, 31 and 36-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on June 5, 2004.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

The Claims 1, 11, 12, 30, 31 and 36-39 are readable on the claimed invention as indicated by Applicant in Paper No. 20.

Response to Arguments

Election/Restriction

Applicant argues that the Examiner did not address Claim 32 in the previous Office action; and, therefore Applicant requests that the Examiner address the merits of Claim 32 in the Office action herein. Applicant further argues, "In view of this omission, it is the applicant's position that any subsequent action by the examiner cannot be made final with respect to the rejection of the claims. To do so would preclude applicants the opportunity to address the examiner's rejections on the whole and individually with respect to claim 32." Applicant's arguments have been fully considered but are found unpersuasive since the basis of Applicant's arguments are not commensurate in scope to claims readable on the elected invention, namely the plant species of *Napoleonaea imperialis* and the solvent species of methanol. For instance, Applicant indicated that Claims 1, 11, 12, 30, 31 and 36-39 are readable on the elected species, in a previous Office action in response to a restriction requirement. Since the subject matter of Claim

32 is directed to a non-elected species, namely ethyl acetate as a solvent, the Office was not required to prosecute and examine Claim 32 on the merits; and, therefore, the Office is not required to prosecute Claim 32 in the present Office action, since Applicant has not amended the subject matter to read on the elected invention.

Applicant's amendment to Claim 39 overcomes the objection made in the previous Office action. However, the subject matter of Claim 39 as presently drafted is directed to a non-elected invention, namely ethyl acetate as a solvent. Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 39 is withdrawn from consideration as being directed to a non-elected invention.

This application contains Claims 2-10, 13-29 and 33-35 drawn to an invention nonelected with traverse but without explanation in Paper No. 20; as well as Claims 32 and 39. Please note that portions of the claim language of Claims 32 and 39 encompass limitations of an invention drawn to a nonelected species. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The claims have been examined insofar as they read on the elected invention, namely the plant species of *Napoleonaea imperialis* and the solvent species of methanol.

Claims 1, 11, 12, 30, 31 and 36-38 are under examination.

Claim Rejections - 35 USC § 102

Claims 1, 11, 12, 30 and 31 remain rejected under 35 U.S.C. 102(b) as being anticipated by Ekpendu et al. (U). Applicant's arguments have been fully considered. However, the rejection remains for the reasons set forth in the previous Office action and for the reasons set forth herein.

Applicant's first argument is directed to the idea that the Examiner concludes that Ekpendu "teach methanol, hexane and ethyl acetate extracts of the root of *Napoleonaea imperialis* and that the teaching inherently includes seeds and powdered seeds of *Napoleonaea imperialis*". Applicant further argues, "Thus the examiner concludes that Ekpendu et al., anticipate the applicant's claim by disclosing a method of extracting components from *N. imperialis*." Applicant's arguments have been fully considered but are not deemed reliable since nowhere in the previous Office action does the Examiner set forth that Ekpendu teaches either a method of extracting components from the claim-designated plant or that the prior art reference inherently includes seeds and powdered seeds of the claim-designated plant. Applicant is kindly invited to revisit the previous Office action, wherein the Examiner clearly sets forth the basis and reasoning why Ekpendu anticipates the claimed subject matter. Applicant's interpretation of the Examiner's rendering of the Ekpendu' reference is made without merit.

Secondly, Applicant argues that Ekpendu fails to anticipate the instantly claimed invention because, "Ekpendu, et al., disclose hydrolyzed hexane, ethyl acetate and methanolic compounds (see Ekpendu, et al., page 76) that begin with the crude extract

obtained for the root bark of *N. imperialis*". Applicant also argues that the teachings of Ekpendu are not directed to determining biological activity of the crude extract but rather to identifying compounds present therein known traditional plants. Further arguments made by Applicant appear to be directed to the idea that the research interest of the first inventor of the present application identified *N. imperialis* seeds as having antileishmanial activity. Finally, Applicant argues that Ekpendu fails to anticipate the instantly claimed invention because Ekpendu teaches organic solvent extracts obtained from the root bark of *N. imperialis*, and not the extracts from the seeds themselves. However, Applicant's arguments are neither persuasive nor commensurate in scope to the limitations of the claimed invention, since nowhere in the claims, as presently drafted, does Applicant direct the claimed invention to any particular type of biological activity of the claim-designated methanol extract, much less antileishmanial activity; and, moreover Applicant is reminded that the subject matter of the rejected claims do not preclude a methanolic extract of root bark, as taught by the anticipatory teachings of Ekpendu. For all of the above reasons, Applicant's arguments are neither persuasive nor commensurate in scope to the limitations of the claimed subject matter because Ekpendu teaches a methanol extract of the root bark of *Napoleonaea imperialis*, as well as, hexane and ethyl acetate extracts thereof. Ekpendu does not expressly teach the methanol extract of the claim-designated plant material as a biologically active extract. However, the plant material, the source of the material, and the solvent used in the making of the plant extract are one and the same as instantly claimed by Applicant. Therefore, a biologically active extract of the methanolic extract of the root bark of

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Napoleonaea imperialis taught by Ekpendu is inherent to the referenced extract, absent evidence to the contrary.

Applicant is invited to review the following:

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

The reference anticipates the claimed subject matter.

Claims 1, 11, 12, 30, 31 and 36-38 remain rejected under 35 U.S.C. 102(b) as being anticipated by Kapundu et al. (V). Applicant's arguments have been fully considered. However, the rejection remains for the reasons set forth in the previous Office action and for the reasons set forth herein.

Applicant argues that Kapundu fails to anticipate the instantly claimed invention because, "The methanolic extract, as disclosed by Kapundu, et al., is a first step in a two-step process for identifying the structure [that is a prosapogenin structure after the seed saponin of *Napoleonaea imperialis* is hydrolyzed]", whereas, Applicant's invention is directed to a methanol extract obtained from the powdered seeds of *Napoleonaea imperialis* for testing efficacy against *Leishmania* and other pathogens. Applicant further argues that the methanol and ethanol seed fractions of the claim-designated plant disclosed by Applicant exhibit inhibitory effects against the growth of *Leishmania* promastigotes and that the extract is obtained without hydrolysis. Each of Applicant's

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arguments have been fully considered but they are neither persuasive nor commensurate in scope to the limitations of the instantly claimed invention since nowhere in the claims, as presently drafted, does Applicant direct the claimed invention to any particular biological activity much less activity against Leishmania.

Applicant is unclear as to how the Examiner establishes an argument for inherency: "To note, Kapundu, et al., is further directed to compound identification, thus necessitating the hydrolysis step. Based on these unobvious distinctions between the applicant's invention and the Kapundu, et al., reference, it is unclear how the examiner establishes an argument for inherency." The Examiner has carefully considered Applicant's position that the Kapundu' reference fails to teach the instantly claimed invention and Applicant's reasoning for the distinction between what is disclosed by Applicant and what is taught by the prior art reference. However, Applicant's arguments are not persuasive because Kapundu clearly teaches a methanol extract from powdered seeds of *Napoleonaea imperialis*, on page 615, Column 2, lines 11-12. While Kapundu does teach identification of compounds contained therein the methanolic seed extract, thus necessitating a hydrolysis step of the extract, such disclosure by Kapundu does not negate the fact that Kapundu expressly teaches a methanolic extract obtained from powdered seeds of the claim-designated plant. Therefore, while Kapundu does not expressly teach that the prior art methanolic plant extract has biological activity *per se*, biological activity is inherent to the extract taught by Kapundu because the source of the plant, the particular plant material from the source plant, and the solvent used in the making of the plant extract taught by Kapundu are one and the same as instantly

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claimed by Applicant. Therefore, a biologically active extract of the methanolic extract of powdered seeds of *Napoleonaea imperialis* taught by Kapundu is inherent to the referenced extract, absent evidence to the contrary.

The Office recognizes the budgetary restraints of Applicant; however, absent the filing of a formal 132 affidavit by Applicant, the Examiner's resources are limited in establishing a distinction from what is instantly claimed by Applicant and what is taught by the prior art.

Applicant is invited to review the following:

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

The reference anticipates the claimed subject matter.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Michele Flood
Primary Examiner
Art Unit 1655

June 12, 2006


MICHELE FLOOD
PRIMARY EXAMINER